IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ELMER HEISNER, Individually and on Behalf of JAYNE HEISNER,	)	
Plaintiff,	)	
v.	)	**No. 08-C-593**
	)	
GENZYME CORPORATION, a Massachusetts Corp.	)	**Honorable David H. Coar**
Defendant.	)	
	)	
	)	

MEMORANDUM OPINION AND ORDER

Before this Court is Defendant Genyzme's ("Defendant") Motion to Dismiss Plaintiff Elmer Heisner's ("Plaintiff") Third Amended Complaint. On May 21, 2009, Plaintiff filed his Third Amended Complaint containing three counts: strict liability (Count I), negligence (count II), and negligence per se (Count III). For the reasons stated below, Defendant's Motion to Dismiss on all counts is GRANTED.

I. Background

On January 19, 2006, Jayne Heisner, wife of Elmer Heisner, underwent surgery to remove an ovarian cyst. To prevent potential post-surgical adhesions, a Seprafilm barrier, made and marketed by Defendant, was placed into her body. Seprafilm is a Class III medical device

approved by the United States Food and Drug Administration ("FDA") pursuant to its premarket approval (PMA) process. Seprafilm is composed of chemically modified hyaluronic acid and carboxymethylcellulose. Individuals who have an allergy to the source animal or microorganism that synthesized the hyaluronic acid may have an increased risk of side effects and the potential to develop an allergic response. Jayne Heisner developed an intense fibrous reaction of the small intestines with collections of foreign body cells. She died on February 22, 2006.

On January 28, 2009, Plaintiff filed a seven-count complaint against Defendant seeking damages in connection with the death of his wife. After Defendant filed a motion to dismiss the original complaint, Plaintiff filed a five-count amended complaint. Defendant argued that Plaintiff's claims were preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetics Act ("FDCA"). 21 U.S.C. § 360c *et seq.* On July 25, 2008, this Court granted Defendant's motion to dismiss. *See Heisner v. Genzyme*, No. 08-CV-593, Mem. Op. and Order (July 25, 2008). The Court concluded that Plaintiff's allegations could not form the basis of his claims because their lack of specificity prevented the Court from determining whether his claims were preempted under 21 U.S.C. § 360k(a). In the interests of justice, Plaintiff was granted leave to replead.

Plaintiff filed his Second Amended Complaint on September 3, 2008. In his amended pleadings, Plaintiff supplemented his tort claims with allegations that Defendant failed in its annual reporting requirements in the years following Jayne Heisner's death. Defendant moved to dismiss on September 17, 2008. Upon review, the Court found that Plaintiff failed to state a claim for strict liability, negligence, or negligence per se because the alleged omissions, occurring after Mrs. Heisner's death, could not have proximately caused her injury. Plaintiff's breach of warranty claim was preempted by the MDA, and his remaining allegations consisted of

the same vague statements contained in his earlier complaints. As a result, on April 30, 2009, this Court again granted Defendant's motion to dismiss, permitting Plaintiff to replead only Counts I, II, and III. *See Heisner v. Genzyme,* No. 08-CV-593, Mem. Op. and Order (Apr. 30, 2009). Plaintiff filed his Third Amended Complaint, the subject of the instant motion to dismiss, on May 21, 2009.

II. Standard of Review

The purpose of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) is to test the sufficiency of a complaint. *Weiler v. Household Finance Corp.*, 101 F.3d 519, 524 n. 1 (7th Cir.1996). To survive the motion, a complaint need only describe the claim in sufficient detail to give the defendant fair notice of the claim and its basis. Fed. R. Civ. P. 8(a)(2); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, (2007). A plaintiff's factual allegations must suggest a plausible, rather than merely speculative, entitlement to relief. *Tamayo v. Blagojevich*, 526 F.3d 1074, 1083 (7th Cir. 2008); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Twombly*, 550 U.S. at 555. That is, the complaint must present "enough facts to raise a reasonable expectation that discovery will reveal evidence" supporting the plaintiff's allegations. *Twombly*, 550 U.S. at 556. In ruling on a motion to dismiss, the court must construe the complaint in the light most favorable to the plaintiff, accepting as true the well-pleaded allegations, and drawing all reasonable inferences in plaintiff's favor. *Tamayo*, 526 F.3d at 1081. "In ruling on a 12(b)(6) motion, a district court may take judicial notice of matters of public record." *Anderson v. Simon*, 217 F.3d 472, 474-75 (7th Cir. 2000).

III. Analysis

The preemption clause of the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act ("FDCA") provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement ---
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The MDA therefore preempts any claim alleging requirements different from, or in addition to, federal requirements. *See Riegel v. Medtronic*, 552 U.S. 312, 329-30 (2008); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997). The Supreme Court has clarified that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 329-30.

A. "Parallel" Claims

The question confronting the Court is whether any of Plaintiff's claims parallel the MDA. A state requirement is "parallel" to a federal requirement, and thus not expressly preempted, if the requirements are "genuinely equivalent." *McMullen v. Medtronic*, 421 F.3d 482, 489 (7th Cir. 2005). For example, nothing prevents a state from creating a damages cause of action when the federal government has found a manufacturer to be in noncompliance with FDA

requirements. *See Riegel*, 552 U.S. at 330. But state and federal requirements are not equivalent if a manufacturer could be held liable under state law while complying with federal requirements. *See McMullen*, 421 F.3d at 489.

Plaintiff argues that Defendant violated a state common law duty to update Seprafilm's product label upon acquiring information regarding the dangerous nature of devices containing hyaluronic acid.[1] The Third Amended Complaint suggests that this common law requirement "parallels" the federal requirement set forth in the FDA Changes Being Effected ("CBE") regulations. The cited CBE provisions permit a drug manufacturer to implement labeling changes that "add or strengthen a contraindication, warning, precaution, or adverse reaction" during the pendency of a supplemental application with the FDA. *See* 21 C.F.R. § 314.70. However, as Plaintiff concedes in his response brief, the CBE regulations to which his complaint refers only apply to drug products, not medical devices. *Id.* The FDCA defines "drug" and "device" differently. *See* 21 U.S.C. § 321(g)-(h). Plaintiff's failure to plead a relevant statute alone gives this Court sufficient grounds to dismiss all related claims.

Had the Third Amended Complaint correctly identified the pertinent regulation as 21 C.F.R. § 814.39(d)(1-2), as belatedly asserted by Plaintiff in his briefs, this Court would still be obliged to dismiss. 21 C.F.R. § 814.39 permits drug device manufacturers to temporarily amend a label pending FDA approval of the proposed changes. However, the Seventh Circuit has held that "[b]ecause § 814.39 permits, but does not require, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a

[1] In the years preceding Jayne Heisner's death, Defendant allegedly learned that devices containing hyaluronic acid accounted for 96% of all adverse events occurring in Genzyme products. (Pl. Resp. Br. At 8-9; Compl. ¶ 51.) This statistic is drawn from the FDA's Manufacturer and User Facility Device Experience Database ("MAUDE"), which publishes all adverse events reported by Defendant to the FDA. (Compl. ¶ 21.)

warning imposes an additional obligation." *McMullen*, 421 F.3d at 489. In other words, § 814.39 does not impose a duty "genuinely equivalent" to the duty that Plaintiff claims exists under state common law. *See id.* As such, the MDA preempts all negligence and strict liability claims turning on Defendant's failure to provide supplemental warnings. (Compl. ¶¶ 32, 44-47).

B. Sufficiency of the Allegations

To the extent that Plaintiff pleads any claims not preempted by the MDA, his allegations lack the specificity required to put Defendant on notice of the basis of those claims.

The Court first addresses Plaintiff's strict liability claim. To properly plead strict liability, Plaintiff must allege, among other things, that an injury resulted from an unreasonably dangerous condition of a product. *See Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008). It is unclear from the pleadings what, precisely, Plaintiff considers to be unreasonably dangerous about Seprafilm. Plaintiff implies that it could be the presence of hyaluronic acid, (Compl. ¶¶ 33-34), Defendant's failure to report adverse events to the FDA, (Compl. ¶¶ 29-31), or the failure to warn users about these adverse events, (Compl. ¶ 32). Insofar as Plaintiff alleges that the presence of hyaluronic acid in Seprafilm is the defect at issue, Plaintiff's claim is preempted. State law cannot impose requirements differing from those of the FDA, and the FDA approved Seprafilm while fully informed of the dangers of hyaluronic acid through pre-market approval testing. *See Riegel*, 552 U.S. at 324-25; (Compl. ¶ 18). If the alleged defect arises from inadequate original or supplemental warnings, such a claim is also preempted for the reasons provided above. Finally, failure to report adverse events to the FDA may violate the FDCA, but does not constitute a product "condition" or defect.

Meanwhile, the language supporting Plaintiff's negligence claim include the same vague statements rejected by this Court in the earlier complaints. (Compl. ¶¶ 37-39.) To be sure, Plaintiff utilizes more words, but verbosity cannot substitute for factual allegations. *Compare* (Compl. ¶ 39(L))("[Genzyme] [f]ailed to provide the FDA with satisfactory postapproval reports concerning 'related devices' containing hyaluronic acid."), *with* (Compl. ¶¶ 40-43) ("Genzyme failed to use reasonable care by failing to provide unpublished reports as to "related devices" containing hyaluronic acid, especially in light of concerns over the near statistical significance of adverse events in Seprafilm abdominal trials."). Even with the additional phrases, Plaintiff's allegations are nothing more than the sort of formulaic recitation of elements rejected by the Supreme Court in *Twombly*, 550 U.S. at 555, and *Iqbal*, 129 S.Ct. at 1949-50.

Plaintiff's negligence per se claim suffers from identical deficiencies, producing more verbiage to no avail. The two facts that Plaintiff does allege are lifted from the Second Amended Complaint. (Compl. ¶ 54(D),(G).) As outlined by this Court's April 2009 Memorandum Opinion, these omissions could not have served as the proximate cause of Jayne Heisner's injury because they occurred after her death. *See Kalata v. Anheuser-Busch Cos.*, 581 N.E.2d 656, 661 (Ill. 1991) (plaintiff must show that defendant's statutory violation was the proximate cause of his injury in order to prevail on a negligence per se claim).

In sum, Plaintiff's allegations are insufficient to place Defendant on notice as to the nature of the claims against it. Accordingly, his Third Amended Complaint must be dismissed.

IV. Conclusion

For the foregoing reasons, Defendant's Motion to Dismiss Plaintiff's Third Amended Complaint is GRANTED in full. Counts I, II, and III of Plaintiff's Third Amended Complaint are DISMISSED WITH PREJUDICE.

Enter:

/s/ David H. Coar

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David H. Coar
United States District Judge

Dated: **March 8, 2010**